K052039

AUG 11 2005

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date:	July 22, 2005
Name of Submitter:	GE OEC Medical Systems, Inc. 384 Wright Brothers Drive Salt Lake City, UT 84116 801-328-9300
Corresponding Official:	Susan Schmidt, Engineer - Safety & Regulatory
Device Proprietary Name:	GE OEC Altitude
Classification Name:	Image Intensified Fluoroscopic X-ray System with Image Processing System
Common/Usual Names:	Fluoroscopic Imaging System
Substantial Equivalence:	The GE OEC Altitude is substantially equivalent to the: • AngioSpeed VC marketed by Shimadzu Corporation which consists of the MH-200S (K943545) and DAR-2400-15B/30B (K955395).

Indications for Use

GE OEC Altitude is a Fluoroscopic Imaging System designed to provide fluoroscopic images of the patient during diagnostic, surgical and interventional angiography and cardiology procedures.

General Description

GE OEC Altitude is an image intensified fluoroscopic fixed C-arm system. It consists of a C-arm that supports a high-voltage generator, x-ray tube, x-ray controls, image intensifier and flat panel display monitors. The system consists of a Ceiling suspended C-arm support (MH-200S), digital substraction system (DAR-9000) and a High Voltage generator (UD150B-40). It is designed to perform linear and rotational motions that allow the user to position the x-ray imaging components at various angles and distances with respect to the patient, and supports image processing and recording devices. This system can be used in conjunction with a mobile or fixed surgical table.

Interfaces are provided for optional peripheral devices such as thermal or laser printers, VCR's, and monitors. Video outputs are compatible with CCIR format for international markets and DICOM 3.0 (optional).

GE OEC Medical Systems, Inc. intends to market, install and distribute the OEC Altitude. Shimadzu will be acting as the contract manufacturer designing, fabricating and assembling the MH-200S, DAR-9000 and UD150B-40 components of the OEC Altitude.

Summary of Studies

GE OEC Altitude was evaluated to the appropriate performance standards and IEC 60601-1 International Medical Equipment Safety standard, IEC 60601-2-28 Particular Requirements of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis and IEC 60601-2-32 Particular Requirements of Associated Equipment for X-Ray Equipment for Safety of GE OEC Altitude. The Product OEC Altitude is comparable to the currently marketed AngioSpeed VC which consists of the MH-200S (K943545) and DAR-2400-15B/30B (K955395).

Conclusion

It is the opinion of GE that GE OEC Altitude is substantially equivalent to the Predicate Product Shimadzu AngioSpeed VC which consists of the MH-200S (K943545) and DAR-2400-15B/30B (K955395). Usage of GE OEC Altitude does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2005

Ms. Susan Schmidt, RAC
Engineer – Safety & Regulatory
GE OEC Medical Systems, Inc.
384 Write Brothers Drive
SALT LAKE CITY UT 84116

Re: K052039
Trade/Device Name: GE OEC Altitude
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: July 22, 2005
Received: July 28, 2005

Dear Ms. Schnidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Applicant:	GE OEC Medical Systems, Inc.
510(k) No. (if known):	K052039
Device name:	GE OEC Altitude
Indications for use:	GE OEC Altitude is a Fluoroscopic Imaging System designed to provide fluoroscopic images of the patient during diagnostic, surgical and interventional angiography and cardiology procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

David A. Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052039

(Optional Format 1-2-96)